

Remarks/Arguments:

1. Claim Status

Claims 1-7, and 9-17 are pending in the current Application and stand rejected.

Presently, claims 1, 10, and 16 have been amended in order to comply with certain claim formalities. In addition, claim 1 has also been amended. The amendments are supported throughout the specification as filed, and in particular at, for example, paragraphs [0017], [0033], [0037], and [0041]. Furthermore, Applicant submits new claim 18. New claim 18 is supported throughout the specification as filed and indicated above, and additionally, at paragraphs [0039], and [0041].

The amendments contain no new matter and do not raise any new issues of patentability. Therefore, the Applicant requests that the Examiner enter the presently amended claims and new claim 18. Applicant believes that the claims are allowable over the cited art and notification to that effect is respectfully requested.

This listing replaces all prior versions, and listings of claims in the application.

2. Claim Objections

The Examiner objects to claims 1, 10, and 16 because of certain informalities relating to 35 U.S.C. § 112, sixth paragraph. In particular, the Examiner notes that the claims recite “means to” instead of “means for,” which typically invokes the auspices of 112, sixth paragraph.

The Applicant has amended claims 1, 10, and 16 such that the claims are now in accordance with the formalities required by 35 USC 112, sixth paragraph. The claims, as filed, clearly indicated the Applicant’s intent to invoke 35 USC 112, sixth paragraph, based on the recitation of the word “means” followed by a specific function to be performed by structures described in the specification. Therefore, in view of the amendment, the Applicant respectfully requests that the Examiner withdraw this claim objection.

3. Claim Rejections Under 35 U.S.C. § 103(a)

3.1. Present Rejection

The Examiner rejects claims 1-7 and 9-17 under 35 U.S.C. § 103(a) as being unpatentable over Biel (USPN 6,048,359) in view of Svanberg et al. (USPN 7,037,325). Briefly, the Examiner states that Biel discloses a phototherapeutic apparatus comprising light delivery probes 14; a plurality of radiation sources 22; multiple radiation output ports; and means 12 for controlling power output levels of the radiation emitted through each radiation output port. The Examiner relies on Svanberg as showing that waveguides connected to light sources were known in the art.

3.2. The Present Invention

The instant claims are drawn to an apparatus that is optimized for performing photodynamic therapy (PDT) procedures. Importantly, the device is surprisingly effective for performing PDT because it provides for greater flexibility of use in comparison to prior devices. See, U.S. v. Adams, 383 U.S. 39, 40 (1966) (held, a combination was not obvious because, although the elements were known in the prior art, they worked together in an unexpected manner). In particular, the instantly claimed device comprises multiple radiation output ports, wherein each output port is connected to multiple radiation sources via an optical connection. Each radiation source comprises a diode unit comprising at least one diode emitter. Accordingly, the radiation output at each of the output ports can be independently varied, separately from the others, while simultaneously in use. Therefore, the claimed invention allows the user to vary the distribution of radiation delivery, spatially and temporally, in an almost infinite number of ways to insure that the ideal amount of radiation power is delivered to each discrete location within the tissue.

In addition to the flexibility described above, the claimed invention provides numerous unexpected advantages over prior devices including the ability to deliver different power ranges to multiple positions simultaneously while being able to individually control and calibrate each delivery point with the single source. Also, because each optical couple receives radiation from multiple radiation sources, the device is capable of providing a greater range of radiation output than prior devices. In addition, the instantly claimed device is capable of supplying radiation to multiple interstitial delivery systems.

3.3. Comments

Obviousness is determined from the perspective of a person of ordinary skill in the art at the time of the invention. Graham v. John Deere Co. of Kansas City, 383 U.S. 1 (1966). In Graham the Supreme Court set out a framework for applying the statutory language of section 103, which includes (i) making a determination of the scope and content of the prior art; (ii) ascertaining the differences between the prior art and the claims at issue; and (iii) resolving the level of skill in the art. Id. at 17-18. In addition, the court recommended the consideration of other, “secondary considerations” including commercial success, long felt but unsolved needs, and the failure of others in order to make the final determination of obviousness or nonobviousness of the subject matter. Id. In addition to the factors set forth in Graham, the prior art must teach or suggest every element of the invention as arranged in the claims, enable the claimed invention, and impart a reasonable likelihood of success. W.L. Gore & Associates, Inc. v. Garlock, Inc., 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984).

Also, while the teaching, suggestion, motivation (TSM) test is no longer considered dispositive of obviousness in all cases, the Supreme Court in KSR v. Teleflex did affirm the usefulness of its application in the overall consideration of obviousness. 82 USPQ2d 1385, 1397 (U.S. 2007).

As discussed above, the instantly claimed device comprises multiple radiation sources incorporated into the device. The multiple radiation sources are optically connected to each radiation output port, which is adapted to receive a waveguide. The device further includes a means to independently control the power output emitted through each individual radiation output port simultaneously. This is in stark contrast to prior devices in which the power output can only be modulated proportionately in all radiation emitters simultaneously.

In particular, Biel (USPN 6,048,359) shows a probe 14 which consists of one or more light emitting devices 22 secured to the shaft of the probe. As distinguished from the claimed invention, the probe described by Biel is, itself, inserted into a tissue body 16. Also, as the Examiner concedes, Biel fails to teach or suggest a device having multiple radiation ports that are adapted to accept a waveguide. The Examiner does not address the fact that Biel similarly fails to

teach or suggest a means for independently controlling radiation output at each radiation source simultaneously. Based on the deficiencies of Biel, the Examiner cites Svanberg et al. (USPN 7,037,325). Svanberg, however, does not compensate for the gaps in Biel's teachings, and instead, merely shows a waveguide connected to a single light source. Contrary to the Examiner's statement, Svanberg does not teach or suggest a device having multiple light output ports.

Therefore, Biel, alone or in combination with Svanberg, fails to teach, suggest or provide a person of skill in the art a reason to make a device having multiple radiation output ports each of which is optically connected to multiple radiation sources; i.e., multiple radiation sources converge their energy on a single output port. Biel seeks to deliver diffused light as a uniform dosage within the tissue, and by placing the radiation sources directly in the implantable probe. As such, Biel obviates the need for a waveguide. In particular, Biel shows an alignment grid 18 that can hold multiple probes, each probe is connected via a single electric couple 28 to a single power source 12. The person of skill in the art would readily understand that the modulation of the power output from Biel's power source 12 would result in the concomitant modulation of radiation output from all of the probes 14 simultaneously. However, Biel does not teach or suggest a device capable of independent modulation of radiation output from each individual probe simultaneously. As such, the amount of radiation being emitted from any probe in the alignment grid of Biel would be varied in the same proportion as the others, and therefore, would not be independently controllable as required by the instant claims.

Furthermore, the Federal Circuit has long held that it is improper to combine references where a reference teaches away from their combination or if the suggested combination of references would require a change in a basic principle under which the reference construction was designed to operate. See, In re Grasselli, 713 F.2d 731, 743 (Fed. Cir. 1983); In re Sponnoble, 405 F.2d 578, 587 (CCPA 1969) ("references taken in combination teach away since they would 'produce a seemingly inoperative device.'"); In re Caldwell, 319 F.2d 254, 256 (CCPA 1963) ("reference teaches away if it leaves the impression that the product would not have the property sought by the applicant"); In re Ratti, 270 F.2d 810, 813 (C.C.P.A. 1959). Because Biel's implantable probe is both the radiation source and the site of radiation emission, a person of skill in the art would not have been motivated to combine this device with an output port or a waveguide, as shown by Svanberg, because the resulting device would no longer operate as

intended and as taught. Therefore, according to the standard espoused in cases such as Sponnoble, the current rejection should be withdrawn.

However, even assuming, *arguendo*, that the device resulting from a combination of Biel and Svanberg would be operative for performing PDT methods as presently taught, which it would not, the combination still does not provide for multiple radiation output ports independently connected to multiple radiation sources, wherein the radiation output from each of the individual output ports can be adjusted simultaneously.

The fact that these limitations from the claims are omitted from the analysis indicates that the invention is *not* being properly viewed as a whole, and therefore, the analysis for purposes of obviousness is flawed. W.L. Gore & Associates, Inc. v. Garlock, Inc., 721 F.2d 1540 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984) (distilling an invention down to the “gist” or “thrust” of an invention disregards the requirements that all elements of the invention be taught, and that the subject matter be analyzed “as a whole.”). It is impermissible within the framework of the patent law to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art. In re Wesslau, 147 USPQ 391, 393 (C.C.P.A. 1965).

As indicated above, Biel merely shows an alignment grid 18 that can hold multiple probes, each probe is connected via a single electric couple 28 to a single power source 12. Biel’s device would not allow for the ability to independently control the radiation output of each probe individually. Similarly, Biel does not teach, suggest or enable a person of skill in the art to make the claimed device. Svanberg, however, does not compensate for the gaps in the teachings of Biel. Svanberg shows only a single radiation source connected to a single radiation conductor, wherein one or more radiation conductors are disposed within a series of discs. Biel, alone or in combination with Svanberg, does not teach or suggest multiple radiation output ports, wherein each is connected to multiple radiation sources, and wherein the individual output ports can be differentially and simultaneously controlled.

One advantage of the device of the instant claims, as compared to that of Biel and/or Svanberg, is that it provides for the differential modulation of radiation emitted from each output port simultaneously. The resulting system allows for delivery of non-uniform or variable light

doses. Surprisingly, the radiation can be effectively modulated, temporally and spatially, while in use. As such, the claimed invention reduces or eliminates the need for cumbersome placement devices such as those taught by Biel and Svanberg. Also, the multiple radiation sources connected to each radiation output port in the present invention allows for a broader range of potential radiation output. The Board has long held that non-enabling inventions should not be considered as prior art. See, Ex parte Humphreys, 24 USPQ2d 1255, 1262 (BPAI 1992) (“We reverse this [section 103] rejection...As set forth above in regard to the enablement rejection for these claims, we have concluded that those skilled in the art would not be enabled as of the filing date of this application to practice the methods called for by these claims throughout their scope...”). Because the cited combination of references fails to teach, suggest or enable the invention as recited in the claims, the references are not sufficient to render the claims *prima facie* obvious. As such, the instant rejection should be withdrawn for at least this additional reason.

Finally, maintaining the present rejection would amount to the application of impermissible hindsight. The Supreme Court in KSR affirmed that there must be something else in the prior art other than the hindsight gained from knowing that the inventor chose to combine these particular things in this particular way. 82 USPQ2d at 1397; See also Uniroyal, Inc. v. Rudkin-Wiley Corp., 837 F.2d 1044, 1051 (Fed. Cir. 1988). The mere fact that references can be combined or modified does not render the combination obvious unless prior art also suggests the desirability and enables the combination. In re Mills, 916 F.2d 680 (Fed. Cir. 1990). As the Board has long recognized, that which is within the capabilities of one of skill in the art is NOT synonymous with that which is obvious. Ex parte Gerlach, 212 USPQ 471 (BPAI 1980). As discussed above, the combination of Biel and Svanberg does not teach each and every element as arranged in the instant claims, and certainly does not enable the claimed invention. Therefore, only through the improper application of hindsight reasoning could an obviousness rejection be maintained.

Because the Examiner has not raised a *prima facie* case of obviousness the rejection under 35 USC 103(a) should be withdrawn in its entirety. Notice to this effect is respectfully requested. Also, because the reasons above are sufficient to overcome the rejections, Applicant has not explored, nor do they now present, other possible reasons for traversing such rejections. Nonetheless, Applicant expressly reserves the right to do so, if appropriate, in any future response or proceeding.

Conclusion

The current Amendments and Remarks are presented in response to the Final Office Action in order to put the claims in condition for allowance. The foregoing is believed to be fully responsive to this office action. Applicants respectfully submit that all claims are in condition for allowance, which action is expeditiously requested. All amendments and cancellations are made without prejudice and disclaimer and may be made for reasons not explicitly stated or for reasons in addition to ones stated.

If the Examiner believes that a telephone conference with Applicants' attorneys would be advantageous to the disposition of this case, the Examiner is cordially requested to telephone the undersigned. If the Examiner has any questions in connection with this paper, or otherwise if it would facilitate the examination of this application, please call the undersigned at the telephone number below.

Applicant believes that fees for a Request for Continued Examination (\$405) and two-month extension of time (\$230) for a small entity are currently due in association with entry of the present Amendment. Therefore, the Commissioner is hereby authorized to debit \$635.00 to Deposit Account No. 50-3569. However, in the event that any fee(s) has been inadvertently overlooked and is required, the Commissioner is hereby authorized to debit any required fees or credit any overpayment to Deposit Account No. 50-3569.

Respectfully submitted,

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